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09/879,660	06/12/2001	Eric Dupont	014985.0012	2949

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,660

Applicant(s)

DUPONT ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-7,9,11,13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,12 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 10 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 8-19, dipeptide as the unit complexed to a copper metal ion, and antitumor agent in claim 16 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the election of antitumor agent in claim 16 should be a species election because claim 16 is a Markush-type claim, thus is generic to the members of the Markush group, and claim 16 has the unity of invention because the members of the Markush group share a common utility which is the members of the group can all be used in composition of claim 12, therefore, it is improper for the Patent Office to refuse to examine the subject matter of claim 16. This is not found persuasive because the compounds of claim 16, which include anti-inflammatory agent, antitumor agent, anti-oxidant agent, and anti-collagenolytic agent, do not meet the structural requirement for the unity of invention within a Markush group. As indicated in MPEP 803.02, it states that unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature disclosed as being essential to that utility. For example, corticosteroid is an anti-inflammatory agent, cisplatin is an antitumor agent, vitamin E is an anti-oxidant agent, and tetracycline is an anti-collagenolytic agent, which are different structures with different functions as recited in the claim. The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 9, 11, 13 and 15 are directed to amino acids complexed to a copper metal ion, thus, they are non-elected invention and withdrawn from consideration. Therefore, claims 8, 10, 12, 14, and 16-19 are examined.

Claim Objections

2. Claims 8 and 16 are objected to because the claim contains non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pallenberg *et al.* (U. S. Patent 6,017,888, January 25, 2000).

Pallenberg *et al.* teach peptide-copper complexes and compositions containing same stimulate the growth of hair on warm-blooded animals, where the peptide can be a dipeptide (e.g., Gly-His) or a dipeptide analog (column 2, lines 24-34; column 3, line 38-column 5, line 30; Table 2, Structure A), and the peptide-copper complex has a ratio of peptide to copper ranging from 1:1 to 3:1, preferably 1:1 to 2:1 (column 2, lines 35-37; claim 8). The compositions contain the peptide-copper complexes in an amount ranging from 0.1% to 20% by weight (column 9, lines 10-14; Table 3), where the complex in the composition is 5%, it corresponds to 0.25 mM (assuming the complex is (Gly-His)₂-Cu) and is in the range of the complex used in the instant application (0.23 mM or 0.66 mM for compound 33 in Tables V and VII of the specification; claim 12). Claims 8 and 12 are anticipated by the reference because the two dipeptide units having both amino and carboxyl groups form the same type of complex with a copper ion as indicated in the instant application (See the structure of the complex at page 24),

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therefore, the (dipeptide)₂-Cu complex in the reference would have been expected to have the same physical and chemical properties as the claimed complex.

4. Claims 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arena *et al.* (J. Inorg. Biochem. 50, 31-45 (1993)).

Arena *et al.* teach a dipeptide-copper complex and a composition containing the complex has cytotoxic and cytostatic activity against cancer cell lines. Where the dipeptide is His-His or Leu-Leu, and the dipeptide-copper complex has a ratio of peptide to copper of 2:1 (Table 1; claim 8). The composition of the dipeptide-copper complex contains the copper in an amount of 3×10^{-6} to 3×10^{-4} mole/dm³ (page 39; Table 4), which corresponds to 0.003 to 0.3 mM, and the concentration of 0.3 mM is in the range of the complex used in the instant application (0.23 mM or 0.66 mM for compound 33 in Tables V and VII of the specification; claim 12). Claims 8 and 12 are anticipated by the reference because the two dipeptide units having both amino and carboxyl groups form the same type of complex with a copper ion as indicated in the instant application (See the structure of the complex at page 24), therefore, the (dipeptide)₂-Cu complex in the reference would have been expected to have the same physical and chemical properties as the claimed complex.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8, 12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arena *et al.* (J. Inorg. Biochem. 50, 31-45 (1993)) taken with Dupont (U. S. Patent 6,383,522, priority date March 11, 1997).

Arena *et al.* teach a dipeptide-copper complex and a composition containing the complex has cytotoxic and cytostatic activity against cancer cell lines, where the dipeptide-copper complex has a ratio of peptide to copper of 2:1 and inherent anti-angiogenic activity (Table 1; claim 8 and 12). However, Arena *et al.* do not disclose the composition comprises an anti-tumor agent. Dupont teaches the use of a shark cartilage extract having antitumor activity and an anti-neoplastic agent in antitumor therapy (column 3, lines 9-15; column 4, lines 13-22). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the dipeptide-copper complex having anti-angiogenic activity taught by Arena *et al.* in combination with the shark cartilage extract and an anti-neoplastic agent as taught by Dupont (claims 16-19) in treating angiogenesis-dependent diseases such as cancer because the use of combination therapy would provide higher anti-tumor efficacy without an increase in toxic effect, or would have been expected to have decrease in toxic effects. Thus, the combined references result in the

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claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

6. Claims 10 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Claims 8, 12 and 16-19 are rejected and claims 10 and 14 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

April 30, 2003

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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